



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35  
Public Health Service

Central Region

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Telephone (973) 526-6008

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**Certified Mail  
Return Receipt Requested**

File # 00-NWJ-16

December 29, 1999

Anthony Vasile  
President  
N. V. N., Inc.  
11 Enterprise Avenue  
Secaucus, NJ 07094

Dear Mr. Vasile:

During an inspection on May 24, 1999 at your firm located at the above address, our Investigator documented violations of Section 123 of Title 21, Code of Federal Regulations. The violations of the Fish and Fishery Product (HACCP) regulations cause your product, Honduran frozen spiny lobster tails, to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), whereby your products were prepared, packed or held under insanitary conditions whereby they may have rendered injurious to health.

The inspectional observation of concern was:

- The failure to develop and implement product specifications and affirmative steps for frozen spiny lobster tails to ensure they were processed at the foreign manufacturer in accordance with 21 CFR 123.12(a)(2).

The requirements of that regulation are included as an enclosure to this letter.

This observation was previously reported to you at the conclusion of the September, 1998 FDA inspection and through a letter addressed to you, dated January 28, 1999. That observation was not corrected despite verbal assurances to the investigator at the conclusion of the previous inspection that it would be.

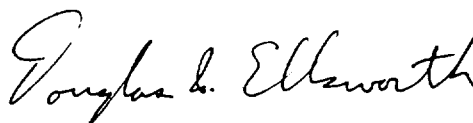
The above item is not intended to be an all-inclusive list of violations. As a warehouse and distributor of human food, you are responsible for assuring that your overall operation and the food products themselves are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

A handwritten signature in cursive script that reads "Douglas I. Ellsworth".

Douglas I. Ellsworth  
District Director

Enclosure